REMARKS

Claims 1-15 are pending in the present application. Claims 1, 2, 6, 8-13, and 15 were amended. Claims 16-21 were cancelled. Support for the amendments to claims 1, 8, and 15 may be found in the specification on page 10, lines 3-9. Reconsideration of the claims is respectfully requested.

I. 35 U.S.C. § 112, Second Paragraph

The examiner has rejected claims 11-13 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicants regard as the invention. Claims 10-13 were amended accordingly. Therefore the rejection of claims 11-13 under 35 U.S.C. § 112, second paragraph has been overcome.

II. 35 U.S.C. § 102, Alleged Anticipation, Claims 1, 3, 8, 10, and 15

The Office Action has rejected claims 1, 3, 8, 10, and 15 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,788,079 to *Bouthiette* et al. This rejection is respectfully traversed.

With regard to claim 1 being anticipated by *Bouthiette*, the Examiner states:

> (A) As per claim 1, Bouthiette discloses a method of packaging medications on demand, the method comprising:
>
> (a) grouping medications into dosage groups, wherein the dosage groups contain at least one element of medication and each element of medication in a dosage group should be taken by a patient at substantially the same time as other elements of medication in the same dosage group (Bouthiette: col. 1, lines 12-19; Fig. 7 and 8);
>
> (b) placing each dosage group of medication into a separate compartment in a package (Bouthiette: col. 1, lines 12-19; Fig. 7 and 8);
>
> (c) covering the components of the package and labeling compartments with patient customized information indicating a time for which the associated medications within the compartment should be taken by a patient, wherein covering the compartments provides a cover such that removal of a dosage group provides an indication to a patient that the dosage group has been taken by the patient (Bouthiette: col. 6, lines 5-10; Fig. 7 and 8)

Office Action dated September 13, 2005, pages 3-4. Amended claim 1 of the present application, which is representative of amended claims 8 and 15 with regards to similarly recited subject matter, recites the following:

> 1. A method of packaging medications on demand, the method comprising:
> grouping medications into dosage groups, wherein the dosage groups contain at least one element of medication and each element of medication in a dosage group should be taken by a patient at substantially the same time as other elements of medication in the same dosage group, and wherein grouping medications into dosage groups comprises *checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group*;
> placing each dosage group of medication into a separate compartment in a package;
> covering the compartments of the package and labeling compartments with patient customized information indicating a time for which the associated medications within the compartment should be taken by a patient, wherein covering the compartments provides a cover such that removal of a dosage group provides an indication to a patient that the dosage group has been taken by the patient. (emphasis added)

With respect to this rejection, a prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). All limitations of the claimed invention must be considered when determining patentability. *In re Lowry*, 32 F.3d 1579, 1582, 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994). Anticipation focuses on whether a claim reads on the product or process a prior art reference discloses, not on what the reference broadly teaches. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 218, U.S.P.Q. 781 (Fed. Cir. 1983). In this particular case, each and every feature of the presently claimed invention is not identically shown or described in *Bouthiette*, arranged as they are in the claims. The *Bouthiette* reference cited by the Examiner does not anticipate the present invention as recited in claim 1, because *Bouthiette* fails to teach each and every element of the claim. Independent claim 1 recites "checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group," features not taught by *Bouthiette*.

The Examiner alleges that in the following section *Bouthiette* teaches the features of grouping medications into dosage groups, wherein the dosage groups contain at least one element of medication and each element of medication in a dosage group should be taken by a patient at substantially the same time as other elements of medication in the same dosage group:

> The invention relates to a kit for "sorting" pills and/or tablets. More particularly, it relates to a kit that can be used by a pharmacist, a nurse or any other person entitled to do so, for the purpose of preparing a set of individual containers containing pills and/or tablets to be administered to a patient. Each of these containers contains the pills and/or tablets that the patient has to take together at the same time during the day over a given period of time (preferably one week).

(*Bouthiette*, column 1, lines 12-19). In the section above, *Bouthiette* teaches a kit for sorting pills and/or tablets. Although *Bouthiette* teaches a kit used by a pharmacist, a nurse, or any other person entitled to do so, and teaches sorting pills and/or tablets into their respective individual containers, no mention is made of checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group.

In contrast to the *Bouthiette* invention, the present invention, as recited in independent claims 1, 8, and 15, teaches the features of checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group. In contrast to the present invention, where a medication database is checked before elements of medication are grouped in a dosage group, in *Bouthiette* pills and/or tablets are sorted into individual containers without any checking of a database. Therefore, *Bouthiette* fails to teach all elements of the claimed invention, and thus fails to anticipate the invention as recited in independent claims 1, 8, and 15.

Furthermore, *Bouthiette* does not teach, suggest, or give any incentive to make the needed changes to reach the presently claimed invention. Absent the Examiner pointing out some teaching or incentive to implement *Bouthiette* checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, one of ordinary skill in the art would not be led to modify

Bouthiette to reach the present invention when the reference is examined as a whole. Absent some teaching, suggestion, or incentive to modify *Bouthiette* in this manner, the presently claimed invention can be reached only through an improper use of hindsight using the Applicants' disclosure as a template to make the necessary changes to reach the invention. Therefore, Applicants respectfully request that the rejection of independent claim 1 under 35 U.S.C. §102 be withdrawn.

Independent claims 8 and 15 recite similar features as claim 1. Therefore, the same distinctions between *Bouthiette* and the claimed invention in claim 1 apply for these claims. For the reasons described above, *Bouthiette* does not contain all elements of independent claims 1, 8, and 15. Hence, *Bouthiette* fails to anticipate the present invention as recited in claims 1, 8, and 15. Since claims 2-7 depend from claim 1 and claims 9-14 depend from claim 8, the same distinctions between *Bouthiette* and the claimed invention in independent claims 1 and 8 apply for these claims. Consequently, it is respectfully urged that the rejection of claims 1-15 have been overcome, and such a notice is respectfully requested.

III. 35 U.S.C. § 103, Alleged Obviousness, Claims 2 and 9

The Office Action has rejected claims 2 and 9 under 35 U.S.C. § 103(a) as being unpatentable over *Bouthiette* in view of *Machblitz* et al. (U.S. Patent No. 4,429,792). This rejection is respectfully traversed.

The Examiner bears the burden of establishing a *prima facie* case of obviousness based on prior art when rejecting claims under 35 U.S.C. § 103. *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). For an invention to be *prima facie* obvious, the prior art must teach or suggest all claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The *Bouthiette* and *Machblitz* references cited by the Examiner do not render obvious the present invention as recited in independent claims 1 and 8, from which claims 2 and 9 depend, because the references fail to teach or suggest all claim limitations. Claim 1 recites "checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group," features not taught or suggested in *Bouthiette* or *Machblitz*, alone or in combination.

The Examiner further states on page 7 of the Office Action that it would be obvious to combine *Bouthiette* and *Machblitz* to arrive at the features of the claimed invention. However, *Machblitz* does not cure the deficiencies in *Bouthiette*. As discussed in the Abstract, *Machblitz* is directed towards a medication dispensing card having sealed compartments for holding single doses of medication. The structure allows unused medication in the inner pack to be recovered from the card without breaking the seal of the individual compartment, permitting reuse. *Machblitz* does not teach or suggest checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claim 2, for example, depends.

Even if *Bouthiette* and *Machblitz* were combinable with *Machblitz*, the result of such a combination would not be the invention as recited in independent claim 1. Rather, such a proposed combination would, at best, result in individual containers that contain medications that a patient has to take together at the same time, substantially as taught in *Bouthiette*, with compartments for holding single doses of medication, in the manner described in *Machblitz*. Even with the proposed combination of *Bouthiette* and *Machblitz*, there would be no ability for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claim 2, for example, depends.

Moreover, neither *Bouthiette* nor *Machblitz* teaches the problem of the present invention or its source. The present invention recognizes the problems involved with grouping medications with potential interactions into dosage groups. Thus, the present invention provides a method for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group. Therefore, one of ordinary skill in the art would not be motivated to modify *Bouthiette* and *Machblitz* in the manner required to form the claimed invention when the problems addressed by the references are reviewed when considering each reference as a whole.

Thus, *Bouthiette* is insufficient, alone or in combination with *Machblitz*, to render obvious the subject invention as recited in claims 2 and 9. As claims 2 and 9 depend from independent claims 1 and 8 demonstrated above to be patentable, claims 2 and 9 are allowable at least by virtue of dependence from a patentable base claim. For the foregoing reasons, Applicants submit that claims 2 and 9 are patentable over *Machblitz* in view of *Bouthiette*, and such a notice is respectfully requested.

IV. 35 U.S.C. § 103, Alleged Obviousness, Claims 4 and 11

The Examiner has rejected claims 4 and 11 under 35 U.S.C. Section 103(a) as being unpatentable over *Bouthiette* in view of *Croce* (U.S. Patent No. 4,762,230). This rejection is respectfully traversed.

The Examiner further states on page 8 of the Office Action that it would be obvious to combine *Bouthiette* and *Croce* to arrive at the features of the claimed invention. However, *Croce* does not cure the deficiencies in *Bouthiette*. As discussed in the Abstract, *Croce* is directed towards a tear oriented package formed of a pair of wall members sealed together about their peripheral edges when aligned with one another. The package can be made to be re-closable by placing a predetermined amount of cohesive material on a pre-selected portion of the package. *Croce* does not teach or suggest checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claim 4, for example, depends.

Even if *Bouthiette* were combinable with *Croce*, the result of such a combination would not be the invention as recited in independent claim 1. Rather, such a proposed combination would, at best, result in individual containers that contain medications that a patient has to take together at the same time, substantially as taught in *Bouthiette*, with a re-closable package, in the manner described in *Croce*. Even with the proposed combination of *Bouthiette* and *Croce*, there would be no ability for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the

same dosage group, as recited in claim 1 of the present invention, from which claim 4, for example, depends.

Moreover, neither *Bouthiette* nor *Croce* teaches the problem of the present invention or its source. The present invention recognizes the problems involved with grouping medications with potential interactions into dosage groups. Thus, the present invention provides a method for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group. Therefore, one of ordinary skill in the art would not be motivated to modify *Bouthiette* and *Croce* in the manner required to form the claimed invention when the problems addressed by the references are reviewed when considering each reference as a whole.

Thus, *Bouthiette* is insufficient, alone or in combination with *Croce*, to render obvious the subject invention as recited in claims 4 and 11. As claims 4 and 11 depend from independent claims 1 and 8 demonstrated above to be patentable, claims 4 and 11 are allowable at least by virtue of dependence from a patentable base claim. For the foregoing reasons, Applicants submit that claims 4 and 11 are patentable over *Bouthiette* in view of *Croce*, and such a notice is respectfully requested.

V. 35 U.S.C. § 103, Alleged Obviousness, Claims 5 and 12

The Examiner has rejected claims 5 and 12 under 35 U.S.C. Section 103(a) as being unpatentable over *Bouthiette* in view of *Kobylevsky et al.* (U.S. Patent No. 6,493,427). This rejection is respectfully traversed.

The Examiner further states on page 9 of the Office Action that it would be obvious to combine *Bouthiette* and *Kobylevsky* to arrive at the features of the claimed invention. However, *Kobylevsky* does not cure the deficiencies in *Bouthiette*. As discussed in the Abstract, *Kobylevsky* is directed towards a central station to which a pharmacy can forward calls at the convenience of the pharmacy. A caller will call in to the pharmacy to request a refill and the call will be automatically routed to the central facility unbeknownst to the caller. A pager system may be utilized to alert the pharmacist to retrieve orders by telephone with a password. *Kobylevsky* does not teach or suggest checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same

dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claim 5, for example, depends.

Even if *Bouthiette* were combinable with *Kobylevsky*, the result of such a combination would not be the invention recited in independent claim 1. Rather, such a combination would, at best, result in individual containers that contain medications that a patient has to take together at the same time, substantially as taught in *Bouthiette*, with a central station for forwarding and receiving telephone calls, in the manner described in *Kobylevsky*. Even with the proposed combination of *Bouthiette* and *Kobylevsky*, there would be no ability for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claim 5, for example, depends.

Moreover, neither *Bouthiette* nor *Kobylevsky* teaches the problem of the present invention or its source. The present invention recognizes the problems involved with grouping medications with potential interactions into dosage groups. Thus, the present invention provides a method for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group. Therefore, one of ordinary skill in the art would not be motivated to modify *Bouthiette* and *Kobylevsky* in the manner required to form the claimed invention when the problems addressed by the references are reviewed when considering each reference as a whole.

Thus, *Bouthiette* is insufficient, alone or in combination with *Kobylevsky*, to render obvious the subject invention as recited in claims 5 and 12. As claims 5 and 12 depend from independent claims 1 and 8 demonstrated above to be patentable, claims 5 and 12 are allowable at least by virtue of dependence from a patentable base claim. For the foregoing reasons, Applicants submit that claims 5 and 12 are patentable over *Bouthiette* in view of *Kobylevsky*, and such a notice is respectfully requested.

VI. **35 U.S.C. § 103, Alleged Obviousness, Claims 6, 7, 13, and 14**

The Examiner has rejected claims 6, 7, 13, and 14 under 35 U.S.C. Section 103(a) as being unpatentable over *Bouthiette* in view of *Sadler et al.* (U.S. Patent No. 4,830,407). This rejection is respectfully traversed.

The Examiner further states on pages 10-11 of the Office Action that it would be obvious to combine *Bouthiette* and *Sadler* to arrive at the features of the claimed invention. However, *Sadler* does not cure the deficiencies in *Bouthiette*. As discussed in the Abstract, *Sadler* is directed towards a label on which a grid-like pattern of detachable recording spaces is provided. The recording spaces are overprinted with a removable coating formulated to provide a readily apparent visual contrast with the underlying coated substrate when the coating is removed. The recording spaces are designated to represent events, times of events, or both, by their association with identifying indicia on the label, and the occurrence or non-occurrence of the same is recorded by removing the coating from the appropriate spaces. *Sadler* does not teach or suggest checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claims 6 and 7, for example, depend.

Even if *Bouthiette* were combinable with *Sadler*, the result of such a combination would not be the invention as recited in independent claim 1. Rather, such a combination would, at best, result in individual containers that contain medications that a patient has to take together at the same time, substantially as taught in *Bouthiette*, with a label that has detachable recording spaces, in the manner described in *Sadler*. Even with the proposed combination of *Bouthiette* and *Sadler*, there would be no ability for checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group, as recited in claim 1 of the present invention, from which claims 6 and 7, for example, depend.

Moreover, neither *Bouthiette* nor *Sadler* teaches the problem of the present invention or its source. The present invention recognizes the problems involved with grouping medications with potential interactions into dosage groups. Thus, the present invention provides a method for checking a database for at least one of a potential interaction between one element of medication

and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group. Therefore, one of ordinary skill in the art would not be motivated to modify *Bouthiette* and *Sadler* in the manner required to form the claimed invention when the problems addressed by the references are reviewed when considering each reference as a whole.

Thus, *Bouthiette* is insufficient, alone or in combination with *Sadler*, to render obvious the subject invention as recited in claims 6, 7, 13, and 14. As claims 6, 7, 13, and 14 depend from independent claims 1 and 8 demonstrated above to be patentable, claims 6, 7, 13, and 14 are allowable at least by virtue of dependence from a patentable base claim. For the foregoing reasons, Applicants submit that claims 6, 7, 13, and 14 are patentable over *Bouthiette* in view of *Sadler*, and such a notice is respectfully requested.

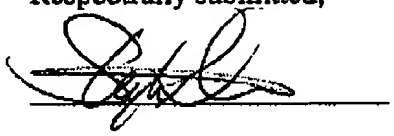
VII. Conclusion

It is respectfully urged that the subject application is patentable over the cited references and is now in condition for allowance.

The Examiner is invited to call the undersigned at the below-listed telephone number if in the opinion of the Examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

DATE: December 12, 2005

Respectfully submitted,



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